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(Original Signature of Member)

111TH CONGRESS
1ST SESSION

H. R. _____

To amend the Public Health Service Act to provide for the licensing of biosimilar and biogeneric biological products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. WAXMAN (for himself, Mr. PALLONE, Mr. DEAL of Georgia, and Mrs. EMERSON) introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act to provide for the licensing of biosimilar and biogeneric biological products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Promoting Innovation and Access to Life-Saving Medicine Act''.

SEC. 2. DEFINITIONS.

(a) LICENSURE.—Section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) is amended—

(1) by striking ''In this section, the term 'biological product' means'' and inserting the following: ''In this section:

''(1) The term 'biological product' means''; and

(2) by adding at the end the following:

''(2) The term 'abbreviated biological product application' means an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under this section or approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

''(3) The term 'reference product' means the single licensed biological product, approved under subsection (a) or (k), against which a biological product is evaluated for demonstration of safety, potency, or purity.

''(4) The term 'final action' means, with respect to an abbreviated biological product application, the Secretary's issuance of a final action letter to the sponsor of an abbreviated biological product application which—

''(A) approves the application; or

''(B) disapproves the application and sets forth in detail an enumeration of the specific

deficiencies in the particular application and of the specific, enumerated actions the sponsor would be required to take in order for the sponsor to receive a final action letter that approves such application.

''(5) The term 'final action date' means, with respect to an abbreviated biological product application, the date by which the Secretary must take a final action on the application pursuant to subsection (k)(13).

''(6) The term 'reviewing division' means the division responsible for the review of an application for approval of a biological product (including all scientific and medical matters, chemistry, manufacturing, and controls).''.

(b) FEES.—

(1) RULE OF CONSTRUCTION.—The definition of a human drug application in section 735(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) shall be construed to include applications under section 351(k) of the Public Health Service Act, as added by section 3, in addition to applications under section 351(a) of such Act.

(2) SUPPLEMENT.—Section 735(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

379g(2)) is amended by adding at the end the following: ''Notwithstanding the preceding sentence, any request for an interchangeability determination under section 351(k) of the Public Health Service Act shall be treated as a supplement for purposes of this part, irrespective of whether such request is included in an application for licensure of a biological product or a subsequent submission.''.

SEC. 3. REGULATION OF BIOSIMILAR AND BIOGENERIC BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262), as amended by section 2, is further amended—

(1) in subsection (a)(1)(A), by inserting ''under this subsection or subsection (k)'' after ''biologics license''; and

(2) by adding at the end the following subsection:

''(k) REGULATION OF BIOSIMILAR AND INTERCHANGEABLE BIOLOGICAL PRODUCTS.—

''(1) BIOSIMILAR.—In this subsection, the term 'biosimilar' or 'biosimilarity', in reference to a biological product, means no clinically meaningful differences between the biological product and the reference product would be expected in terms of the

safety, purity, and potency if treatment were to be initiated with the biological product instead of the reference product.

''(2) INTERCHANGEABILITY.—In this subsection, the term 'interchangeable' or 'interchangeability' means, with respect to a given condition of use, that—

''(A) the biological product is biosimilar to the reference product; and

''(B) if the biological product is intended to be administered more than once to a given patient, the patient can be switched one or more times between the reference product and the biological product without an expected increase in the risk of adverse effects, including a clinically significant change in immunogenicity, or diminished effectiveness, compared to the expected risks from continuing to use the reference product without such switching.

''(3) SUBMISSION OF AN ABBREVIATED BIOLOGICAL PRODUCT APPLICATION.—Any person may file with the Secretary an abbreviated biological product application. Any such application shall include the following:

''(A) Information demonstrating that the biological product and reference product contain highly similar molecular structural features, notwithstanding minor differences in heterogeneity profile, impurities, or degradation patterns.

''(B) Information demonstrating that the biological product is biosimilar to (as defined in paragraph (1)) or interchangeable with (as defined in paragraph (2)) the reference product for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling based upon, in the discretion of the Secretary—

''(i) information derived from chemical, physical, and biological assays, and other non-clinical laboratory studies; and

''(ii) information from any necessary clinical study or studies sufficient to confirm safety, purity, and potency.

Any studies under clause (ii) shall be designed to avoid duplicative and unethical clinical testing.

''(C) Information demonstrating that the biological product and reference product utilize

the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product or can reasonably be determined. If the applicant seeks to rely on a demonstration of biosimilarity or interchangeability for a single condition of use to support approval of additional conditions of use that share the same mechanism or mechanisms of action, information demonstrating that such reliance is scientifically appropriate.

''(D) Information to show that the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling for the biological product have been previously approved for the reference product.

''(E) Information to show that the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product.

''(F) Information demonstrating that the facility in which the biological product is manufactured, processed, packed, or held meets

standards designed to ensure that the biological product continues to be safe, pure, and potent.

''(4) OTHER APPLICATIONS.—Any person, including a person who has not conducted and does not have a right of reference to the studies in the application for a reference product, may submit an abbreviated biological product application under this paragraph for a biological product that differs from, or incorporates a change to, the reference product with respect to one or more characteristics described in subparagraphs (A) through (E) of paragraph (3), including a difference in safety, purity, or potency, so long as the application contains sufficient information to establish the safety, purity, and potency of the biological product for its proposed condition or conditions of use.

''(5) APPROVAL OF BIOSIMILAR OR INTERCHANGEABLE BIOLOGICAL PRODUCTS.—

''(A) DETERMINATION OF BIOSIMILARITY.—Upon review of an application submitted under paragraph (3) for a biological product and any other information available to the Secretary, including information in the application for the reference product, the Secretary shall issue a biosimilar biological product

license for the conditions of use prescribed, recommended, or suggested in the proposed labeling for the product, unless the Secretary finds and informs the applicant (including provision of a detailed explanation) that—

''(i) information submitted in the application and any other information available to the Secretary is insufficient to show that the biological product and the reference product contain highly similar molecular structural features, notwithstanding minor differences in heterogeneity profile, impurities, or degradation patterns;

''(ii) information submitted in the application and any other information available to the Secretary is insufficient to show that the biological product is biosimilar to the reference product for the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed in the application;

''(iii) information submitted in the application and any other information available to the Secretary is insufficient to show that the biological product and reference

product utilize the same mechanism or mechanisms of action for the conditions of use prescribed, recommended, or suggested in the proposed labeling for the biological product, unless the mechanism or mechanisms of action are not known and cannot reasonably be determined for the reference product for such condition or conditions;

''(iv) if the applicant has demonstrated biosimilarity for a single condition of use sharing the same mechanism of action as other conditions of use of the reference product, and has sought approval of one or more such other conditions of use on the basis of such demonstration, information submitted in the application and any other information available to the Secretary is insufficient to show the safety, purity, and potency of one or more such other conditions of use;

''(v) information submitted in the application and any other information available to the Secretary is insufficient to show that the route of administration, the dosage form, and the strength of the biological

product are the same as those of the reference product;

''(vi) information submitted in the application and any other information available to the Secretary is insufficient to show that the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling for the biological product are limited to one or more of the same use or uses as have been previously approved for the reference product;

''(vii) information submitted in the application and any other information available to the Secretary shows (I) the inactive ingredients of the biological product are unsafe for use under the conditions prescribed, recommended, or suggested in the proposed labeling for the biological product, or (II) the composition of the biological product is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

''(viii) information submitted in the application and any other information available to the Secretary fails to demonstrate that the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to ensure that the biological product continues to be safe, pure, and potent;

''(ix) the Secretary has, for reasons of safety, purity, or potency, other than reasons that are unique to the reference product—

''(I) withdrawn or suspended the license of the reference product;

''(II) published a notice of opportunity for hearing to withdraw such license; or

''(III) determined that the reference product has been withdrawn from sale; or

''(x) the application contains an untrue statement of material fact.

''(B) DETERMINATIONS ON INTERCHANGEABILITY.—Subject to subparagraph (C) and paragraph (11), upon issuing a product license

for a biological product under subparagraph (A), the Secretary shall make and publish one of the following determinations:

''(i) Such product is interchangeable with the reference product for one or more specified conditions of use prescribed, recommended, or suggested in the labeling of the biological product.

''(ii) Interchangeability has not been established, but the approved product is as safe and effective for its approved uses as the reference product.

''(C) DETERMINATION OF INTERCHANGEABILITY OF SUBSEQUENT BIOLOGICAL PRODUCT.—If the Secretary determines that an application meets the approval requirements of subparagraph (A), and, prior to the issuance of a product license, the Secretary has made a determination of interchangeability of another biological product and the reference product for which the exclusivity period under paragraph (11) has not expired, the Secretary shall—

''(i) issue the product license for the subsequent biological product; and

''(ii) defer issuing any determination of interchangeability as to the subsequent biological product and the reference product until the exclusivity period under paragraph (11) has expired.

''(6) DESIGNATION OF OFFICIAL NAME.—

''(A) IN GENERAL.—If, pursuant to section 508 of the Federal Food, Drug, and Cosmetic Act, the Secretary determines that designation of an official name for a biosimilar biological product is necessary or desirable in the interests of usefulness or simplicity, the Secretary shall designate the same official name for the biosimilar biological product as the Secretary designated for the reference product.

''(B) LIMITATION.—This paragraph shall not apply to products approved under paragraph (7).

''(C) REPORT TO CONGRESS.—Not later than 5 years after the date of the enactment of this subsection, the Comptroller General of the United States shall submit a report to the Congress on public health and economic impacts associated with practices for designating the official names of biosimilar biological products in

the United States and in other countries that approve biosimilar biological products.

''(7) OTHER APPROVAL PROVISIONS.—The Secretary shall approve an application for a license submitted under paragraph (4) if the application and any other information available to the Secretary, including information in the application for the reference product, are sufficient to establish the safety, purity, and potency of the biosimilar biological product for the proposed condition or conditions of use for such product.

''(8) ESTABLISHING INTERCHANGEABILITY FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

''(A) IN GENERAL.—In an original application or a supplement to an application under this subsection, an applicant may submit information to the Secretary to demonstrate the interchangeability of a biosimilar biological product and the reference product. An applicant may withdraw a request for an interchangeability determination at any time. A request for an interchangeability determination submitted after the filing of an application shall be considered a major amendment to the application. Except as provided in paragraph (11), nothing in

this subsection shall be construed to prohibit the Secretary from making a determination of interchangeability at any time after approval.

''(B) GUIDANCE.—Within 2 years after enactment of this subsection, the Secretary shall issue guidance regarding standards and requirements for interchangeability. The Secretary is authorized to make determinations of interchangeability under paragraph (5)(B) prior to issuing guidance under this subparagraph.

''(9) INTERCHANGEABILITY LABELING FOR INTERCHANGEABLE BIOLOGICAL PRODUCTS.—Except as provided in paragraph (11), upon a determination of interchangeability, the Secretary shall, at the request of the applicant, provide for the label of the interchangeable biological product to include a statement that the biological product is interchangeable with the reference product for the conditions of use prescribed, recommended, or suggested in the labeling for which interchangeability has been established.

''(10) DELAY OF APPROVAL.—

''(A) APPLICABLE DELAY PERIOD.—

''(i) 5-YEAR PERIOD.—If an application under this subsection refers to a bio-

logical product described in clause (i) of subparagraph (B), the Secretary may not approve such application before the expiration of—

''(I) the 5-year period beginning on such product's approval date; or

''(II) such period, as extended under subparagraph (D).

''(ii) 3-YEAR PERIOD.—If an application under this subsection refers to a biological product described in subparagraph (C), the Secretary may not approve such application for the conditions of approval of such product before the expiration of—

''(I) the 3-year period beginning on such product's approval date; or

''(II) such period, as extended under subparagraph (D)

''(B) NO MAJOR SUBSTANCE PREVIOUSLY APPROVED.—

''(i) IN GENERAL.—A biological product is described in this clause if—

''(I) an application is submitted for such product under subsection (a);

''(II) no major substance of the product, nor any highly similar major substance, has been approved in any other application under subsection (a);

''(III) the application submitted for such product is approved after the date of the enactment of this subsection; and

''(IV) the application submitted for such product could not and did not rely on any clinical safety, purity, or potency study in any other application approved under this section or any clinical safety or effectiveness study in any application approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

''(ii) EXCLUSIONS.—Biological products not described in clause (i) include the following:

''(I) Protein biological products that differ in structure solely due to post-translational events, infidelity of translation or transcription, or minor differences in amino acid sequence.

''(II) Polysaccharide biological products with similar saccharide repeating units, even if the number of units differ and even if there are differences in post-polymerization modifications.

''(III) Glycosylated protein products that differ in structure solely due to post-translational events, infidelity of translation or transcription, or minor differences in amino acid sequence, and if they had similar saccharide repeating units, even if the number of units differ and even if there were differences in post-polymerization modifications.

''(IV) Polynucleotide biological products with identical sequence of purine and pyrimidine bases (or their derivatives) bound to an identical sugar backbone (ribose, deoxyribose, or modifications of these sugars).

''(V) Closely related, complex partly definable biological products with similar therapeutic intent, such

as live viral products for the same indication.

The Secretary may by regulation identify additional biological products not described in clause (i).

''(C) MAJOR SUBSTANCE PREVIOUSLY APPROVED.—A biological product is described in this subparagraph if—

''(i) an application is submitted for such product under subsection (a);

''(ii) such product includes a major substance that has been approved in another application under subsection (a), or any highly similar major substance;

''(iii) the application submitted for such product is approved after the date of the enactment of this subsection; and

''(iv) the application submitted for such product contains reports of new clinical investigations (other than pharmacokinetic or pharmacodynamic studies) essential to the approval of the application and conducted or sponsored by the applicant; and

''(v) the product represents a significant therapeutic advance, which may include demonstration of safety, purity, and potency for a significant new indication or subpopulation, other than a pediatric subpopulation.

''(D)(i) SUPPLEMENT.—If a supplement to an application approved under subsection (a) is approved no later than 1 year before the expiration of a period to which the applicant is entitled under subparagraph (A), the period described in subparagraph (A) shall, except as provided in clause (ii), be extended by 6 months if—

''(I) the supplement contains reports of new clinical investigations (other than pharmacokinetic or pharmacodynamic studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement; and

''(II) the change provides a significant therapeutic advance, which may include demonstration of safety, purity, and potency for a significant new indication or

subpopulation, other than a pediatric subpopulation.

''(ii) ADJUSTMENT.—Any period of market exclusivity extended under subclause (I) or (II) of clause (i) for a biological product shall be reduced by 3 months if the organization designated under subparagraph (E) notifies the Secretary that, with respect to any major substance contained in the biological product, the combined annual gross sales in the United States for all biological products—

''(I) containing the major substance; and

''(II) owned or marketed by the applicant or its affiliates;

exceeded $1,000,000,000 in the calendar year preceding approval of the supplement involved.

''(iii) LIMITATION.—Only one extension under this subparagraph may be granted for any biological product.

''(E)(i) DESIGNATION.—The Secretary shall designate an organization other than the Food and Drug Administration to make the determination of combined annual gross sales described in clause (ii). Prior to designating such

organization, the Secretary shall determine that such organization is independent and is qualified to evaluate the sales of pharmaceutical products. The Secretary shall re-evaluate the designation of such organization once every 3 years.

''(ii) NOTIFICATION.—The organization designated under clause (i) shall—

''(I) determine, with respect to each major substance contained in each biological product that is the subject of a pending supplement under subparagraph (D)(i), the amount of the combined annual gross sales in the United States in the preceding calendar year for all biological products—

''(aa) containing the major substance; and

''(bb) owned or marketed by the applicant or its affiliates; and

''(II) notify the Secretary of such determination.

''(F) DEFINITION.—In this paragraph, the term 'approval date' means the date of approval of an application for the biological product under subsection (a).

''(11) EXCLUSIVITY.—

''(A) IN GENERAL.—Upon review of an abbreviated biological product application relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (5)(B) that the second or subsequent biological product is interchangeable for any condition of use, and no holder of a biological product license approved under subsection (a) shall manufacture, market, sell, or distribute a rebranded interchangeable biological product, directly or indirectly, or authorize any other person to manufacture, market, sell, or distribute a rebranded interchangeable biological product, for any condition of use, until the earlier of—

''(i) 180 days after the first commercial marketing of the first interchangeable biological product to be approved as interchangeable for that reference product;

''(ii) one year after—

''(I) a final court decision in favor of the applicant on all patents in

suit in an action instituted under paragraph (18)(C) against the applicant that submitted the application for the first approved interchangeable biological product; or

''(II) the dismissal with or without prejudice of an action instituted under paragraph (18)(C) against the applicant that submitted the application for the first approved interchangeable biological product; or

''(iii)(I) 36 months after approval of the first interchangeable biological product if the applicant has been sued under paragraph (18)(C) and such litigation is still ongoing within such 36-month period; or

''(II) one year after approval in the event that the first approved interchangeable biological product applicant has not been sued under paragraph (18)(C).

For purposes of this subparagraph, the term 'final court decision' means a final decision of a court from which no appeal (other than a petition to the United States

Supreme Court for a writ of certiorari) has been or can be taken.

''(B) REBRANDED INTERCHANGEABLE BIOLOGICAL PRODUCT.—For purposes of this subsection, the term 'rebranded interchangeable biological product'—

''(i) means any rebranded interchangeable version of the reference product involved that the holder of the biological product license approved under subsection (a) for that reference product seeks to commence marketing, selling, or distributing, directly or indirectly; and

''(ii) does not include any product to be marketed, sold, or distributed—

''(I) by an entity eligible for exclusivity with respect to such product under this paragraph; or

''(II) after expiration of any exclusivity with respect to such product under this paragraph.

''(12) HEARING.—If the Secretary decides to disapprove an abbreviated biological product application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on

the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within 30 days after such notice, such hearing shall commence not more than 90 days after the expiration of such 30 days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis, and the Secretary's order thereon shall be issued within 90 days after the date fixed by the Secretary for filing final briefs.

''(13) FINAL ACTION DATE.—

''(A) IN GENERAL.—The Secretary shall take a final action on an abbreviated biological product application by the date that is 10 calendar months following the sponsor's submission of such application, or 180 days following the Secretary's notification to the applicant that its application has been accepted for filing, whichever is earlier.

''(B) EXTENSION.—The final action date provided by subparagraph (A) with respect to an application may be extended for such period of time as is agreed to by the Secretary and the applicant in a jointly executed written agreement that is counter-signed by the Secretary

and the applicant no later than 30 days prior to—

''(i) such final action date; or

''(ii) the date on which any prior extension under this subparagraph expires.

''(14) REQUEST FOR DELAY OF FINAL ACTION.—Subject to paragraph (19)(A)(i) and notwithstanding any other provision of law, the Secretary shall not fail or refuse to take a final action on an abbreviated biological product application by the final action date on the basis that a person, other than the biosimilar biological product applicant, has requested (in a petition or otherwise) that the Secretary refuse to take or otherwise defer such final action, and no court shall enjoin the Secretary from taking final action or stay the effect of final action previously taken by the Secretary, except by issuance of a permanent injunction based upon an express finding of clear and convincing evidence that the person seeking to have the Secretary refuse to take or otherwise to defer final action by the final action date—

''(A) has prevailed on the merits of the person's complaint against the Secretary;

''(B) will suffer imminent and actual irreparable injury, constituting more than irrecoverable economic loss, and that also will threaten imminent destruction of such person's business; and

''(C) has an interest that outweighs the overwhelming interest that the public has in obtaining prompt access to a biosimilar biological product.

''(15) REPORT ON EXTENSIONS OF FINAL ACTION DATE.—The Secretary shall prepare and submit to the President, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate a report regarding any jointly executed written agreement to extend the final action date under this Act within 15 calendar days after the joint execution of any such written agreement.

''(16) REPORT ON FAILURE TO TAKE FINAL ACTION.—The Secretary shall prepare and submit annually to the President, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate a report detailing the specific

and particularized reasons enumerated by the reviewing division for each instance of the Secretary's failure to take final action by the final action date in the previous year.

''(17) REGULATIONS.—The Secretary shall establish, by regulation within 2 years after the date of the enactment of this subsection, requirements for the efficient review, approval, suspension, and revocation of abbreviated biological product applications under this subsection. The Secretary may not use the absence of final regulations as a basis for the Secretary to fail to act on an application submitted under this subsection.

''(18) PATENTS.—

''(A) REQUEST FOR PATENT INFORMATION.—

''(i) IN GENERAL.—At any time, including at the initial stages of development, an applicant or a prospective applicant under this subsection may send a written request for patent information to the holder of the approved application for the reference product. The holder of the approved application for the reference product shall, not later than 60 days after

the date on which the holder receives the request, provide to the applicant or prospective applicant a list of all those patents owned by, licensed to, or otherwise under the control of, the holder of the approved application that the holder believes in good faith relate to the reference product, including patents that claim the approved biological product, any formulation of such product, any method of using such product, any component of such product, or any method or process that can be used to manufacture such product or component, regardless of whether that method or process is used to manufacture the reference product.

''(ii) UPDATES.—For a period of 2 years beginning on the date on which the holder of the approved application for the reference product receives the request for information, the holder shall send to the applicant or prospective applicant updates of its response to the request for information by identifying all relevant patents issued or licensed to the holder after the

initial response under clause (i). Any such update must be provided, in the case of a new patent, not later than 30 days after the date on which the patent is issued and, in the case of a license, not later than 30 days after the date on which the holder obtains the license.

''(iii) ADDITIONAL REQUESTS.—The applicant may submit additional requests under clause (i) for patent information, and each such request shall be subject to the requirements of this paragraph.

''(iv) NOTIFICATION TO PATENT HOLDER.—Within 30 days of receiving a request under this subparagraph, the holder of the approved application for the reference product shall give notice of such request to the owner of any patent licensed to, or otherwise under the control of, the holder that is identified by the holder pursuant to clause (i).

''(B) PATENT NOTIFICATIONS.—At any time after submitting an application under this subsection, the applicant may provide a notice of the application with respect to any one or

more patents identified by the holder of the reference product pursuant to subparagraph (A) or with respect to any one or more patents owned by, licensed to, or otherwise under the control of the holder of the approved application, but not identified pursuant to subparagraph (A). An applicant may submit additional notices at any time, and each notice shall be subject to the provisions of this subparagraph. Each notice shall—

''(i) be sent to the holder of the approved application for the reference product and to the owner of any patent identified by the holder pursuant to subparagraph (A);

''(ii) include a detailed statement of the factual and legal bases for the applicant's belief that the patents included in the notice are invalid, are unenforceable, or will not be infringed by the commercial sale of the product for which approval is being sought under this subsection; and

''(iii) be submitted to the Federal Trade Commission, which shall treat such notice as confidential.

''(C) ACTION FOR INFRINGEMENT.—Within 45 days after the date on which the holder of the approved application for the reference product, or the owner of a patent, receives a notice under subparagraph (B), the holder or patent owner may bring an action for infringement only with respect to the patent or patents included in the notice.

''(D) LIMITATION ON DECLARATORY JUDGMENT ACTIONS.—With respect to any patent relating to a product that is the subject of an application under this subsection, the recipient of a notice under subparagraph (B) with respect to that application may not, prior to the commercial marketing of the product, bring any action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any such patent that was not identified in the notice.

''(E) DECLARATORY JUDGMENT ACTION.—

''(i) IN GENERAL.—With respect to any patent identified in a notification under subparagraph (A) or (B) for which the holder, or the owner of the patent—

''(I) has not brought an action for infringement under subparagraph (C); or

''(II) has brought an action for infringement under subparagraph (C), but subsequently dismissed that action without prejudice;

the applicant may bring an action for a declaratory judgment under section 2201 of title 28, United States Code, that such patent is invalid or not infringed by the biological product at issue.

''(ii) CASE OR CONTROVERSY.—The courts of the United States shall have, and shall exercise, subject matter jurisdiction to hear such an action to the full extent permitted by Article III of the Constitution.

''(F) DISCRETION OF APPLICANTS.—An applicant or prospective applicant for a biosimilar biological product under this subsection may not be compelled, by court order or otherwise, to initiate the procedures set forth in this paragraph. Nothing in this paragraph requires

an applicant or a prospective applicant to invoke the procedures set forth in this paragraph.

''(19) PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS.—

''(A) IN GENERAL.—With respect to a pending application submitted under paragraph (3) or (4), if a petition is submitted to the Secretary that seeks to have the Secretary take, or refrain from taking, any form of action relating to the approval of the application, including a delay in the effective date of the application, the following applies, subject to subparagraph (E):

''(i)(I) The Secretary may not, on the basis of the petition, delay approval of the application unless the Secretary determines, within 30 days after receiving the petition, that a delay is necessary to protect the public health. Consideration of a petition shall be separate and apart from the review and approval of the application.

''(II) With respect to a determination by the Secretary under subclause (I) that a delay is necessary to protect the public health:

''(aa) The Secretary shall publish on the Internet site of the Food and Drug Administration a statement providing the reasons underlying the determination.

''(bb) Not later than 10 days after making the determination, the Secretary shall provide notice to the sponsor of the application and an opportunity for a meeting with the Commissioner to discuss the determination.

''(ii) The Secretary shall take final agency action on the petition not later than 180 days after the date on which the petition is submitted. The Secretary shall not extend such period, even with the consent of the petitioner, for any reason, including based upon the submission of comments relating to the petition or supplemental information supplied by the petitioner.

''(iii) The Secretary may not consider the petition for review unless it is signed and contains the following verification: 'I

certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: [_____]. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to file this petition: [_____]. I verify under penalty of perjury that the foregoing is true and correct.'.

''(B) DENIAL BASED ON INTENT TO DELAY.—If the Secretary determines that a petition or supplement to the petition was submitted with the primary purpose of delaying the

licensure or the approval of a condition of use for a biological product, the Secretary may deny the petition at any point based on such determination. The Secretary may issue guidance to describe the factors that will be used to determine under this subparagraph whether a petition is submitted with the primary purpose of delaying the approval of an application.

''(C) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

''(i) FINAL AGENCY ACTION WITHIN 180 DAYS.—The Secretary shall be considered to have taken final agency action on a petition referred to in subparagraph (A) if—

''(I) during the 180-day period referred to in clause (ii) of such subparagraph, the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulations); or

''(II) such period expires without the Secretary having made such a final decision, in which case the peti-

tion shall be deemed to have been denied.

''(ii) DISMISSAL OF CERTAIN CIVIL ACTIONS.—If a civil action is filed with respect to a petition referred to in subparagraph (A) before final agency action within the meaning of clause (i) has occurred, the court shall dismiss the action for failure to exhaust administrative remedies.

''(D) APPLICABILITY OF CERTAIN REGULATIONS.—The provisions of this section are in addition to the requirements for the submission of a petition to the Secretary that apply under section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations).

''(E) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to the Congress a report that specifies—

''(i) the number of applications under this subsection that were approved during the preceding 12-month period;

''(ii) the number of such applications whose effective dates were delayed by peti-

tions referred to in subparagraph (A) during such period; and

''(iii) the number of days by which the applications were so delayed.

''(F) EXCEPTION.—This paragraph does not apply to a petition that is made by the sponsor of an application under this subsection and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

''(G) DEFINITION.—For purposes of this paragraph, the term 'petition' includes any request to the Secretary, without regard to whether the request is characterized as a petition.

''(20) AUTHORIZATION OF APPROPRIATIONS.—To carry out this subsection, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 and 2011.''.

(b) ADDITIONAL AMENDMENTS.—

(1) VENUE.—Section 1404 of title 28, United States Code, is amended by adding at the end the following:

''(e) VENUE IN CERTAIN PATENT INFRINGEMENT DISPUTES.—

''(1) IN GENERAL.—In any action for patent infringement brought by the holder or owner of the patent pursuant to section 351(k)(18)(C) of the Public Health Service Act, the defendant may move to transfer the action to any other district in which jurisdiction is proper.

''(2) TIMING.—The schedule applicable to a motion under paragraph (1) is as follows:

''(A) A motion under paragraph (1) shall be filed by the defendant no later than 45 days after service of the complaint.

''(B) A response to such a motion, if any, shall be filed no later than 20 days after service of the motion.

''(C) A reply to such response, if any, shall be filed no later than 10 days after service of the response.

''(D) The schedule set forth in this paragraph may be modified only by agreement of all parties.

''(3) RESOLUTION.—When ruling on any motion filed under paragraph (2), the greatest weight shall be given to the following factors:

''(A) The interest in identifying a district court in which the case will be adjudicated expeditiously.

''(B) The strong public interest in obtaining prompt judicial resolution of patent disputes so that the biological product which is the subject of the patent dispute may be brought to market as expeditiously as possible, consistent with fair and prompt resolution of patent disputes.

''(4) NO DELAY.—An action described in paragraph (1) shall proceed as expeditiously as possible while the court considers a motion under this subsection, and the court may not stay the proceedings because a motion under this subsection has been filed.''.

(2) PATENTS.—Section 271(e) of title 35, United States Code, is amended—

(A) in paragraph (2)—

(i) by striking ''or'' at the end of subparagraph (A);

(ii) by adding ''or'' at the end of subparagraph (B);

(iii) by inserting after subparagraph (B) the following:

''(C) a notice described in section 351(k)(18)(B) of the Public Health Service Act, but only with respect to a patent identified in such notice,'';

(iv) in the matter following subparagraph (C) (as inserted by clause (iii) of this subparagraph), by inserting before the period the following: '', or if the notice described in subparagraph (C) is provided in connection with an application to obtain a license to engage in the commercial manufacture, use, or sale of a biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent'';

(B) by adding at the end the following paragraph:

''(6)(A) This paragraph applies in the case of a patent—

''(i) which is disclosed in a response to a request for patent information pursuant to subparagraph (A) of section 351(k)(18) of the Public Health Service Act;

''(ii) with respect to which a notice was provided pursuant to subparagraph (B) of such section; and

''(iii) for which an action for infringement of the patent—

''(I) was brought after the expiration of the 45-day period described in subparagraph (C) of such section; or

''(II) was brought before the expiration of the 45-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

''(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the person who submitted the notice described in subparagraph (A)(ii) infringed the patent, or that any person induced or contributed to infringement of the patent, shall be a reasonable royalty.

''(C) The owner or licensee of a patent that should have been disclosed in response to a request for patent information made by an applicant pursuant to subparagraph (A) of section 351(k)(18) of

the Public Health Service Act, but that was not timely disclosed under that subparagraph, may not bring an action under this title for infringement of that patent.'';

(C) in paragraph (5)—

(i) by adding ''(A)'' in front of ''Where''; and

(ii) by adding the following subparagraph:

''(B) Where a person has provided a notice described in subparagraph (B) of section 351(k)(18) of the Public Health Service Act, and neither the holder for the approved biological product or the owner of a patent identified in the notice brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice was received, the courts of the United States shall, to the extent consistent with the Constitution, have and exercise subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgement that such patent is invalid or not infringed.''; and

(D) in paragraph (4), by striking ''in paragraph (2)'' in both places it appears and inserting ''in subparagraphs (2)(A) or (2)(B)''.

(3) CONFORMING AMENDMENTS.—

(A) TITLE 28.—Section 2201(b) of title 28, United States Code, is amended by inserting before the period the following: '', or section 351 of the Public Health Service Act''.

(B) PUBLIC HEALTH SERVICE ACT.—Subjection (j) of section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by inserting ''or subsection (k)'' after ''subsection (a)''.

(c) REVIEW OF APPLICATIONS SUBMITTED DURING EXCLUSIVITY PERIODS.—

(1) USER FEE GOALS.—

(A) REVISION.—Within 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services, in consultation with the relevant stakeholders, shall revise the PDUFA reauthorization performance goals and procedures with respect to the user fee goals for abbreviated biological product applications under section 351(k) of the Public Health Service Act, as added by subsection (a) of this sec-

tion, that are submitted more than 2 years in advance of the expiration of any period of exclusive marketing to which the reference drug is entitled under subsection (k)(10) or subsection (l) of section 351 of the Public Health Service Act, as added by subsection (a) of this section and section 4 respectively.

(B) CONSIDERATIONS.—In revising the user fee goals for applications described in subparagraph (A), the Secretary shall consider—

(i) the need to provide sufficient time so that a decision on whether to approve the application can be made in advance of the expiration of any exclusivity, and considering the possibility that amendments will be necessary after the initial decision and prior to approval; and

(ii) the importance of conserving agency resources.

(2) REVIEW PRIORITIES.—In setting priorities with respect to the review of applications described in paragraph (1)(A), the Secretary shall take into account the number of years in advance of the expiration of any exclusivity granted to the reference drug that an application was submitted.

(3) SUBMISSION OF REVISED PERFORMANCE GOALS TO CONGRESS.—The Secretary shall, within 30 days after revising the PDUFA reauthorization performance goals and procedures under this subsection, submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a letter describing the revised goals and the basis for such revisions.

(4) DEFINITIONS.—In this subsection:

(A) The terms ''abbreviated biological product application'' and ''reference product'' have the meanings given to those terms in section 351(i) of the Public Health Service Act, as amended by section 2(a).

(B) The term ''PDUFA reauthorization performance goals and procedures'' means the performance goals and procedures of the Food and Drug Administration, agreed to for purposes of the reauthorization of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 279g et seq.; relating to the prescription drug user fee program) for fiscal year 2008 and succeeding fiscal years.

SEC. 4. PEDIATRIC STUDIES OF BIOLOGICAL PRODUCTS.

Section 351 of the Public Health Service Act (42 U.S.C. 262), as amended by section 3, is further amended by adding at the end the following:

''(l) PEDIATRIC STUDIES.—

''(1) APPLICATION OF CERTAIN PROVISIONS.—The provisions of section 505A of the Federal Food, Drug, and Cosmetic Act shall, except as inconsistent with this section, apply to biological products approved under subsection (a) or (k) of this section to the same extent and in the same manner as such provisions apply to drugs approved under subsection (c) or (j), respectively, of section 505 of the Federal Food, Drug, and Cosmetic Act.

''(2) MARKET EXCLUSIVELY FOR NEW BIOLOGICAL PRODUCTS.—If, prior to approval of an application that is submitted under subsection (a) of this section, the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any

such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act—

''(A) the period for such biological product referred to in subparagraph (A) of subsection (k)(10), including any extension under subparagraph (D) of such subsection, is extended by 6 months; and

''(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

''(3) MARKET EXCLUSIVITY FOR ALREADY-MARKETED BIOLOGICAL PRODUCTS.—If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) of this section for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group

for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act—

''(A) the period for such biological product referred to in subparagraph (A) of subsection (k)(10), including any extension under subparagraph (D) of such subsection, is extended by 6 months; and

''(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

''(4) EXCEPTION.—The Secretary shall not extend the period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3) is made later than 9 months prior to the expiration of such period.''.